

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 30 May 2001 (30.05.01)	Applicant's or agent's file reference 46664 + A
International application No. PCT/IT00/00359	Priority date (day/month/year) 15 September 1999 (15.09.99)
International filing date (day/month/year) 12 September 2000 (12.09.00)	
Applicant COCOLA, Adriano et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

05 April 2001 (05.04.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
--	--

**(19) World Intellectual Property Organization
International Bureau**



(43) International Publication Date
22 March 2001 (22.03.2001)

(10) International Publication Number
WO 01/20532 A2

PCT

- (51) **International Patent Classification**⁷: G06F 19/00

(21) **International Application Number**: PCT/IT00/00359

(22) **International Filing Date**:
12 September 2000 (12.09.2000)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
FI99A000191 15 September 1999 (15.09.1999) IT

(71) **Applicant (for all designated States except US)**: **DIESSE DIAGNOSTICA SENESE S.P.A.** [IT/IT]; Via San Vitore, 36/1, I-20123 Milano (IT).

(72) **Inventors; and**

(75) **Inventors/Applicants (for US only)**: **COCOLA, Adriano** [IT/IT]; Via San Marco, 110, I-53100 Siena (IT). **MELONI, Michele** [IT/IT]; Piazza F.B. Petrucci, 18, I-53100 Siena (IT).

(74) **Agents**: **MANNUCCI, Michele et al.**; Via della Scala, 4, I-50123 Firenze (IT).

(81) **Designated States (national)**: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States (regional)**: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— Without international search report and to be republished upon receipt of that report.

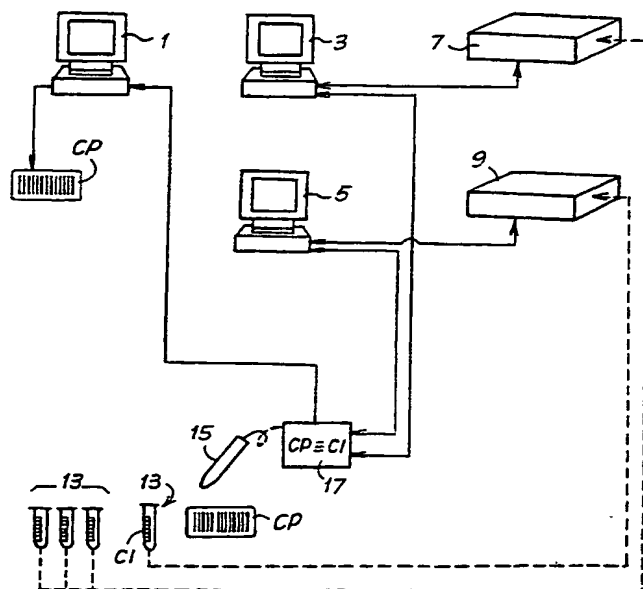
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND MEANS FOR DATA MANAGEMENT IN A LABORATORY



(57) Abstract: A data processing system for data management in an analytical laboratory is described, and comprises, in combination, a central electronic computer (1) for acquiring the patient data, and for generating a patient code (CP) for each patient acquired; means (15) for acquiring an identification code (CI) associated with each container (13) for laboratory analysis; means (17) for combining each of said acquired identification codes with a corresponding patient code; at least one analyzer (7; 9) which carries out at least one analysis on a biological specimen contained in the containers placed in it.

WO 01/20532 A2



METHOD AND MEANS FOR DATA MANAGEMENT IN A LABORATORY
DESCRIPTION

Technical Field

The present invention relates to a method for data management in an analytical laboratory, particularly in a laboratory for analyzing biological specimens from patients.

The invention also relates to a system for data management in an analytical laboratory.

Finally, the invention relates to a container for use in the method and with the system mentioned above.

Prior Art

In the era of total quality, high standards of safety and reliability are required in the diagnostic field as in other areas. In spite of the efforts made by manufacturers of equipment and materials for diagnostic analysis, however, situations occur in the course of application in the analytical laboratory and/or in a hospital complex which give rise to errors and thus reduce the quality of the results obtained.

At the present time, containers of various types, particularly test tubes, cups, racks, microplates and others, are used for carrying out a multiplicity of analyses of the diagnostic type. In the present description and the following claims, the term "container" denotes any device suitable for containing a biological specimen to be analyzed. The specimen can be a biological specimen (for example blood, serum or urine) or a specimen of a different kind, for example a fragment of tissue, or even a DNA specimen. The container can be a container in which has been placed the specimen taken directly from the patient, or a container in which has been placed a fraction of a specimen taken previously and placed in an intermediate container. In this case, reference is made, for example, to a "mother test tube" and a "daughter test tube". The containers can be simple vessels for the biological specimen, or can also contain a preparation which is designed to react with the specimen for the execution of the subsequent analyses.

In the present description and the attached claims, the term "analytical

- 2 -

laboratory" denotes any structure in which analyses of the diagnostic type or the like are carried out on biological specimens taken from patients.

There are currently various methods for data management in analytical laboratories, which also vary in respect of the degree of automation of each structure. For example, in a particularly simple management method, the patient's name is handwritten on a white label provided on the container. In a more advanced method, a patient code is associated with each patient whose data are acquired by a central computer (Host Computer). In the subsequent processing, the patient is identified by means of the patient code instead of by his own forename and surname. In this case, it is the patient code that will be written on the white label applied to the container.

In other procedures, a sheet with attached self-adhesive labels bearing the patient code in the form of a bar code is printed at the moment of generation of the patient code. The patient will then go with these labels to the specimen-taking center, where the operator will take the biological specimen, for example blood. In this case, the operator does not have to write the name or the patient code on the white label previously applied to the container, but can simply detach the self-adhesive label from the sheet supplied by the patient and apply the label to the container in which the biological specimen for analysis is placed.

The container or containers identified in this way are then sent to one or more pieces of equipment which carry out the required analyses. In the present description, these pieces of equipment will be indicated summarily by the term "analyzers". The term "analyzer" denotes any equipment capable of carrying out an analysis on a biological specimen. While carrying out analyses, the analyzers acquire the patient code appearing on the container and then combine the patient code with the result of the analysis. The analyzers can be controlled by their own incorporated microprocessors, by electronic computers interfaced with the analyzers, or by a remote computer, for example the central computer which has acquired the patient data and generated the patient code.

In some cases, one or more containers are sent to pieces of equipment



which take the biological specimen from a single container ("mother test tube") and distribute it into other containers ("daughter test tubes"), for carrying out different analyses on the same specimen. In this case, the pieces of equipment are programmed according to a job sheet so that they are capable of determining which containers the fractions of the biological specimen of which patient have been distributed into.

The analyzers and any machines which distribute the specimen from "mother" test tubes to "daughter" test tubes are connected to the central computer in a suitable way. The central computer thus receives the results of the analyses carried out by the various analyzers associated with the patient codes of the individual patients initially acquired. In this way it proceeds to print the report.

Even if there is maximum automation of the data management system in the analytical laboratory, errors due to various causes may occur and give rise to serious consequences in that the patients receive results relating to biological specimens of different patients.

A first set of errors originates from the system of labeling with patient codes. A first and more evident error is the human error which consists in attaching a label bearing the bar code of a patient to the wrong container. This error is commonly caused by the uncomfortable conditions in which the personnel have to work in the specimen-taking room.

This is because the operator in the specimen-taking center is in direct contact with the biological material from which he must protect himself by using, at least, rubber gloves, and in these conditions he must detach the adhesive label with the printed patient code and attach it to the patient specimen-taking container in front of him after having identified it on the job sheet.

Specimen-taking containers vary according to their manufacturers, and this gives rise to numerous problems, since the area for the application of the label to the container is not always compatible with the size of the label. Additionally, the label has to be applied to the container so that it is as straight as possible, to prevent the analyzer reading system, which is specific for each



piece of equipment, from having difficulties in identification, from identifying the label incorrectly, or from being simply unable to read it. In this respect, the quality of printing of the patient code printed by the central computer is also very important, since there are considerable differences in sensitivity between
5 different code readers, according to the type and programming of each reader.

The consequences of all these possible events can easily be imagined; they range from the allocation of a different result to the blocking or slowing of the data stream of the routine, due to bottlenecks in the patient code
10 recognition model downstream of the central computer.

The use of a sheet carrying a plurality of self-adhesive labels, the number of which usually exceeds that of the containers which are actually to be used, is a source of waste, since for each patient several unused labels are frequently thrown away. The presence of left over labels increases the risk
15 that left over labels will be erroneously applied to containers for a different patient. Moreover, the use of self-adhesive labels makes it necessary to print the whole patient sheet on self-adhesive material which is expensive.

The operation of detaching and applying the adhesive labels is time-consuming and laborious and reduces the time available for personnel
20 responsible for specimen taking, thus increasing the waiting time for specimen taking. In certain cases, this drawback is overcome by the employment of an auxiliary operator responsible solely for applying the labels, so that the person taking the specimen is released from this task. However, this significantly increases personnel costs, or diverts personnel from more important activities.

25 The overall quality of the result is ultimately affected by this.

There are also difficulties due to the lack of a uniform standard applied in the field. Indeed, when two or more systems interact and have to exchange data, it is necessary to identify a simple, reliable model that is as general as possible (the "standard"), to which all the elements of the system must
30 conform.

The systems currently in use in various laboratories for the flow of data between analyzers and the central computer give rise to the following



paradox. On one hand, the manufacturers of diagnostic systems market a vast range of instruments and containers which have a high level of internal compatibility. On the other hand, there are companies (software houses), managing the data processing systems of the analytical laboratories, which produce models that are similar to, but different from, each other. The instruments are interfaced with the network. The laboratory personnel has to make the various components (analyzers, containers, management programs of the central computer and the network) compatible with each other to some degree, while minimizing costs and errors.

The paradox lies in the fact that neither the manufacturers nor the software houses have a model which can act as a standard, and consequently, whenever a manufacturer's new data processing system is installed in a laboratory, considerable efforts are required to make the system compatible, and this also happens in each laboratory for all the new instruments that arrive.

Objects of the Invention

A first object of the present invention is to provide a method and a system for laboratory data management which makes it possible to minimize management errors and thus improve the quality of the system.

A further object of the present invention is to provide a system and a method which enable data to be managed in an analytical laboratory in a more reliable way and with savings of materials and personnel.

Yet another object of the present invention is to provide a system and a method which enable equipment and containers from different sources to be made easily compatible, without the requirement for major adaptation work in the programming and design of the data processing system.

An object of the invention is also to provide a data management method which can be applied in existing systems, without the necessity of modifying the communication protocols of the computer network, and without the necessity of reprogramming the computers themselves.

Another object of the invention is to provide a system and a method which enable manufacturers to produce analyzers and containers in which the



quality of the reading of the codes applied to the containers is optimized, while bottlenecks, slowing of the data stream, and reading errors are reduced.

Brief Description of the Invention

These and other objects and advantages, which the following text will make clear to persons skilled in the art, are achieved with a method comprising the steps of:

- providing a plurality of containers for the laboratory analysis of biological specimens, each container being associated with its own identification code;
- associating a patient code with a patient to be subjected to analysis;
- for each container used for said patient, generating in a data processing system a combination of said patient code with said identification code of the corresponding container;
- carrying out, by means of at least one analyzer, at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined with the identification code of the container or containers, into the data processing system.

This method is characterized in practice in that each container used for the biological specimens is identified by its own identification code. This code can be applied during the production of the container, directly by the manufacturer, who can thus carry out the labeling (or other means of applying the identification code) in an optimal way, according to (a) the characteristics of the container; (b) the characteristics of the code reader with which any analyzer produced by the same manufacturer is equipped. The method according to the invention therefore has the advantage that each analyzer has to read, with its own reader, only one identification code which has advantageously been applied to the container by the manufacturer of the container, who may also be the manufacturer who has produced the analyzer. Thus there is an optimal level of compatibility between the container (and its code) and the analyzer (and its reader), with consequent elimination of reading errors.

The patient will be provided with a single medium bearing his own



patient code, instead of a set of self-adhesive labels. The printing of the medium bearing the code is fast and economical. There is no waste of material, and it is not necessary to use expensive self-adhesive material.

The operator responsible for specimen taking does not have to carry out any complex operation of detaching and applying adhesive labels, but can simply read the patient code and the identification codes of the container or containers, thus causing the data processing system to acquire these codes which are combined with each other. Therefore, the human errors due to incorrect combination of adhesive labels with containers are eliminated. The acquisition of the codes is extremely rapid and requires a minimum of manual activity, and can easily be carried out even when protective rubber gloves are worn.

In greater detail, the method according to the present invention can be implemented with the following steps:

- 15 ◦ generating a patient code for at least one patient on whom at least one analysis is to be carried out and storing said patient code in a data processing system. This operation is carried out at the moment of admission of the patient, by means of the central computer;
- 20 ◦ placing a biological specimen from said patient in said at least one container. This operation is carried out, for example, in the specimen-taking room in the case of a blood specimen. In this step, the operator causes the data processing system to read the patient code and the identification codes of the containers used;
- 25 ◦ carrying out at least one analysis of said specimen in at least one analyzer. In this step, the analyzer automatically reads (by means of its own reader) the identification code of the container and enters it into the data processing system to which it is connected, while associating it with the results of the analysis;
- 30 ◦ using the data processing system to associate the results of the analysis or analyses with the patient code, and then with the patient identified by said patient code, by means of the combination of the patient code with the identification code.



The method has the further advantage that the data processing system holds data in which the result of each analysis is combined with an identification code which identifies in a unique way the container of the analyzed specimen. This facilitates any quality control, for example where the
5 result of the analyses is disputed. The problems related to anti-doping analysis may be considered in this connection.

Theoretically, the patient code and the identification code can be codes of various types, for example alphanumeric codes which the operator responsible for specimen taking and any operator responsible for running the
10 analyzer enter into the data processing system by means of a keyboard. However, in accordance with what has already been implemented, these codes are advantageously automatically readable codes, so that the intervention of the operators is minimized. For example, they may be bar codes or other optical reading codes. In this case, the operator responsible for
15 specimen taking, or an assistant, can cause the patient codes and the identification codes to be read to a unit of the data processing system by means of an optical reader wand or other reader. Alternatively, the codes can be magnetic codes. This can be the case with the patient code in particular, since the patient could be provided with a magnetic card bearing his personal
20 data and his patient code, supplied by the analytical laboratory to the patient on his first admission. The card can then be used for subsequent services provided by the same laboratory. Optical reading codes (particularly bar codes) may be preferable for the identification of the containers, since analyzers are now already equipped with optical readers. The use of patient
25 codes and identification codes of the same kind, readable with the same instruments, simplifies the operations of acquiring and combining these codes in the data processing system.

The method according to the present invention can easily be implemented in an existing management system of the type described above.
30 Indeed, in a possible embodiment, it is provided that: (a) the patient code is generated by a central computer of the data processing system by a similar method to that used up to the present, with the difference that the code can



be printed on a single plain paper medium and not on a set of self-adhesive labels; (b) the combination of the patient code with the identification code is carried out by means of a unit of the data processing system other than the central computer, and therefore this unit can be suitably programmed and interfaced without interfering with the programming of the central computer; and (c) the result of the analysis, sent to the central computer, is associated directly with the patient code, rather than with the identification code of the container. Thus the central computer continues to receive at its input the same data for whose management it is currently programmed (patient code; result of the analyses from the analyzer). The difference from the conventional method consists in the fact that the analyzer reads the identification code of the container, instead of the patient code, which has been produced and applied to the container in an optimal way with respect to the characteristics of the reader of the analyzer. The result of the analysis, combined with the identification code of the container of the analyzed specimen, is then processed further to recombine it with the patient code which is combined with the identification code. The latter data item (patient code + result of the analysis) is the one that will be sent to the central computer, in a way completely identical to that used in conventional systems. The recombination of the result of the analysis and the patient code can be carried out by means of the same unit which has carried out the combination of the patient code with the identification code, or by means of a different unit.

In this embodiment, the method can be implemented in existing systems and can be executed even when analyses of the conventional type, in other words those using the conventional combination of container and patient code, are carried out in the same system. This is because the basic elements of the data processing system continue to operate in conventional ways, the operations relating to the method according to the present invention being "transparent" to the central computer.

In an improved embodiment of the method according to the invention, however, the central computer can be programmed to receive from the individual analyzers the results of the analyses combined with the



identification codes of the containers. In this case, the same central computer will receive, from the unit supplied to the operator in the specimen taking room, the combination of the patient code and the identification codes of the containers assigned to the individual patient, and will be programmed in such a way that the patient code is re-associated with the results of the analyses by means of the aforesaid combination. In this embodiment, the method permits simpler processing of the data, but requires the reprogramming of the data processing system and makes it necessary to carry out all analyses by the new method, in other words to have all the containers identified by corresponding identification codes.

On the other hand, in this improved embodiment the method can be used to carry out in a simple way, using the same procedure, even those analyses in which the biological specimen contained in a mother test tube is distributed into a plurality of daughter test tubes, for clinical chemical analysis for example. This is because each daughter test tube will be provided in its turn with an identification code. The equipment which carries out the distribution will read the identification code of the mother test tube and the identification codes of the daughter test tubes and will enable the data processing system (in the central computer directly, for example) to create a combination of the former and the latter, in a way similar to the combination created between the patient code and the identification code of the mother test tube. The combination can also be carried out in a semi-automatic way by an operator using an optical reader wand or other suitable device to read the identification codes of the mother test tube and the daughter test tubes before entering them into the distribution device. The results of the analyses will then be combined with the identification codes of the daughter test tubes. Using a reverse process with a number of steps, it is always possible to combine the results of the analyses with the original patient code. The reverse process will have a number n of steps, with $n = m + 1$ where m is the number of mother-daughter relations.

When the biological specimen is distributed in a rack or in a microplate, where the individual wells cannot be characterized by identification codes,

and where specimens from a plurality of patients are placed in wells in the same microplate or in the same rack, the rack or the microplate will have its own identification code and the individual wells will be identified by coordinates. The analyzer which automatically distributes the biological specimens among the different wells uses a job sheet to associate the
5 identification code of the container from which it takes the specimen with the coordinates of the well or wells of the microplate or rack into which it distributes the fractions of the specimen.

The data processing system according to the invention comprises, in
10 combination,

- a central electronic computer, for acquiring the data on patients on whose biological specimens the analyses are to be carried out, and for generating a patient code for each patient acquired;
- means for acquiring an identification code associated with each container
15 of a plurality of containers for laboratory analysis of biological specimens;
- means for combining each of said acquired identification codes with a corresponding patient code;
- at least one analyzer with means for reading identification codes associated with the containers which are placed in it, said analyzer carrying
20 out at least one analysis on a biological specimen contained in the containers placed in it and supplying to said electronic computer the result of the analyses carried out, combined with data capable of associating said result with the patient to whom the biological specimen belongs.

Further advantageous embodiments of the method and system
25 according to the invention are indicated in the attached claims.

For the application of the method according to the invention, a container for laboratory analysis of biological specimens is provided; this is characterized in that it is provided with an identification code which is unique or absolute, in other words different from those of the other containers used in
30 the laboratory, and preferably of the automatically readable type, to enable the use of the method to be automated and simplified. The container, or the set of containers, each characterized by its own absolute identification code,



also constitute an object of the present invention.

The container may also be provided with an expiry date, after which the container shall not be used. This date can be included in the identification code and/or written in a man-readable form. In the first case, the system in which it is used can be programmed such as to interrupt the analysis if an expired container has been used, this situation being automatically detected by reading the identification code. Additionally or alternatively, the container may be provided with means which render it unusable after the expiry date. For example, for those containers which must be transparent for optical reading, the material they are made of can be such that it becomes opaque after the expiry date. In addition or alternatively the identification code can be printed with an ink which becomes unreadable after the expiry date.

Brief Description of the Drawings

The invention will be more clearly understood from the description and the attached drawing, which shows a practical and non-restrictive embodiment of the invention. More particularly, the drawings show,

in Fig. 1, a diagram of a network consisting of a central computer and a set of peripheral units;

in Fig. 2, an example of a container with an identification code;

in Fig. 3, a flow chart representing the method according to the invention in a first embodiment;

in Fig. 4, a diagram of a network similar to that of Fig. 1, in a second embodiment; and

in Fig. 5, a flow chart representing the method according to the invention in a second embodiment.

Detailed Description of Embodiments of the Invention

Fig. 1 shows schematically a network of units forming a data processing system in which the method according to the present invention can be implemented. The number 1 indicates a central electronic computer (host computer). The central computer 1 is programmed to acquire the patient data and to generate for each patient a patient code CP, which for example is printed in the form of a bar code on a paper medium.

- 13 -

The numbers 3 and 5 indicate two peripheral electronic computers for monitoring and operating corresponding analyzers 7 and 9. The patient whose data have been acquired by the central computer 1 and for whom a patient code CP has been output passes into an area for taking biological specimens, showing his patient code CP, and here an operator takes the specimen and places, for example, the blood (or other biological specimen) in one or more containers 13. Each container 13 is provided with an identification code CI, which is unique and absolute, in other words different for each container 13, for example a bar code printed on a self-adhesive label applied to the container 13 during the production of the container.

An example of a container in the form of a test tube for ESR (erythrocyte sedimentation rate) analysis with its corresponding identification code CI is shown in detail in Fig. 2.

Using an optical reader wand or other equivalent reading device, indicated schematically by 15, the operator who takes the specimen, or his assistant, reads the patient code CP and the identification codes CI of the containers 13 which have to be used for this patient. The number 17 indicates a generic control unit of the reader 15 which acquires the codes CP and CI. The unit 15 can be programmed to permit the acquisition of a patient code and an unlimited number (or a number limited to a maximum) of identification codes relating to the same number of other containers. Software can be used to ensure that it is not possible to read, for example, two patient codes consecutively, in order to prevent errors, and/or that it is not possible to acquire a patient code after the acquisition of a preceding patient code and one or more identification codes CI without the execution of a reset operation.

Thus the unit 17 enables the codes CI and CP, combined with each other, to be entered into the data processing system: each patient code CP will be associated in the data processing system with one or more identification codes CI, relating to the containers in which the operator has placed the patient's biological specimens.

The data read by the unit 17 are sent to the computers 3 and 5 by means of a data line or other suitable means, if necessary by physically

- 14 -

transferring a storage medium such as a diskette or other. The specimens in the containers 13 are transferred physically to the analyzers 7, 9 (as shown by the arrowed broken lines).

The analyzers 7 and 9 comprise corresponding readers (not shown) which read the identification codes CI of the containers 13 placed in them and carry out the specified analyses. Since each type of analysis frequently requires a specific type of container, it is possible to make the identification code CI of the individual container contain additional data relating to the type of analysis for which it is intended. For example, specific containers in which a special reagent is kept can be provided for specific clinical chemical analyses, the type of reagent (and therefore the type of analysis) being indicated by one or more digits of the identification code. At the same time, to enable the operator to easily identify the type of container, containers for different analyses can be distinguished by different shapes, or caps of a particular color for each type of container.

The analyzer receiving a container holding the biological liquid to be analyzed can check, by reading the identification code CI, that the type of analysis for which the container is intended corresponds to the analysis which the analyzer is to carry out, and can emit an error signal when this is not the case.

To enable the different analyzers to determine which analyses are to be carried out for the individual patients, it is possible to use a job sheet by a method similar to that used in conventional systems. The central computer 1 generates a job sheet where the patient code and the type of analysis to be carried out is shown for each registered patient. These data are then entered by an operator by means of a keyboard into the individual analyzers or into the computers controlling them. Any errors at this point do not cause particular problems, being limited to the possible performance of analyses which were not requested or the omission of analyses which were requested. However, there is no possibility of the occurrence of errors of incorrect combination of the patient data with the results of the analysis.

The analyzers 7 and 9 carry out the requested analyses under the



control of the computers 3, 5, and send to the computers 3, 5 the results of the analyses combined with the identification codes CI read from the individual containers 13. These data are then sent to the unit 17 (or another unit which stores the combination of the code CP and the codes CI generated by the unit 17 by the reading of the codes). The unit 17 is connected to the central computer 1 and supplies it with the results of the analysis after it has recombined these with the patient codes on the basis of its knowledge of the correct combination of the identification codes CI (combined with the results of the analyses obtained from the computers 3, 5) and the patient codes CP.

10 The central computer 1 can thus receive the results in the conventional standard format at its input, and does not require reprogramming to execute the described method.

Fig. 3 summarizes the procedure described above, in the form of a flow chart.

15 When the central electronic computer 1 can be programmed in a dedicated way, the system for implementing the method according to the present invention can be simplified as shown in the diagram in Fig. 4, where identical or equivalent parts are indicated by the same reference numbers. This diagram additionally shows an analyzer 8 controlled directly by the central computer 1. The unit 17 is connected directly to the central computer rather than to the peripheral computers 3 and 5. The codes CI combined with each individual code CP read by the reader 15 are thus communicated by the unit 17 to the central computer 1. This computer receives the results of the analyses, combined with the corresponding identification codes CI of the containers 13 either by the analyzers directly (in the case of the analyzer 8) or by the peripheral computers 3, 5 which control the analyzers (in the case of the analyzers 7 and 9). The central computer 1 is programmed so that it can recombine the results of the analyses with the corresponding patient codes CP and then print the results in clear text, by means of the combination

20

25

30

communicated by the unit 17.

When - for example as shown schematically in Fig. 4 - there is a connection between the central computer and the peripheral computers

associated with the individual analyzers, it is no longer necessary to supply the job sheet and enter into the individual analyzers the data relating to the types of analysis to be carried out on the individual patients. These data are supplied directly to the peripheral computers by the central computer 1 which

5 has acquired the patient.

The embodiment of the method described above is summarized in the block diagram in Fig. 5, where (in a similar way to that used in Fig. 3) the symbols $CI_1 \dots CI_n$ indicate the n identification codes of the n containers 13 combined with a given patient code P .

10 It is to be understood that the drawing shows only a possible embodiment of the invention, which can be varied in its forms and arrangements without departure from the scope of protection specified by the following claims.

- 17 -
CLAIMS

1. A method for data management in an analytical laboratory, comprising the steps of:

- 5 • providing a plurality of containers for the laboratory analysis of biological specimens, each container being associated with its own identification code;
- associating a patient code with a patient to be subjected to analysis;
- for each container used for said patient, generating in a data processing system a combination of said patient code and said identification code of
10 the corresponding container;
- carrying out, by means of at least one analyzer, at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined with the identification code of the container or containers, into the data processing system.

15 2. The method according to Claim 1, comprising the steps of:

- generating a patient code for at least one patient on whom at least one analysis is to be carried out and storing said patient code in a data processing system;
- placing a biological specimen from said patient in said at least one
20 container;
- carrying out at least one analysis of said specimen in at least one analyzer, the analyzer reading the identification code of said container and entering into said data processing system the results of the analysis combined with the identification code of said container;
- 25 • using said data processing system to associate the results of the analysis or analyses with the patient code, and then with the patient identified by said patient code, by means of the combination of the patient code with the identification code.

30 3. The method according to Claim 1 or 2, in which said identification code is placed on the corresponding container in a machine-readable format.

4. The method according to Claim 1, 2 or 3, in which said

identification code is placed on the corresponding container at the time of the production or packaging of the container.

5. The method according to Claim 1, 2, 3 or 4, in which said patient code is placed on a medium in a machine-readable format.

5 6. The method according to Claims 3 and 5 at least, in which the combination of the patient code with the identification code is generated by the sequential reading by an automatic reading instrument of the patient code and the identification code, or vice versa.

7. The method according to one or more of Claims 1 to 6, in which
10 said patient code and said identification code are reproduced as bar codes and are optically read to produce said combination.

8. The method according to one or more of Claims 1 to 7, in which said patient code is generated by a central computer of said data processing system; the combination of the patient code with the identification code is
15 carried out by means of a unit of said data processing system other than said central computer; and the result of the analysis, associated with the patient code, is sent to said central computer.

9. The method according to one or more of Claims 1 to 7, in which said patient code is generated by a central computer of said data processing system; the combination of the patient code with the identification code is
20 carried out by means of a unit of said data processing system other than said central computer; and the result of the analysis, associated with the identification code of the containers, is sent to said central computer, the central computer being programmed to associate with the result of the
25 analysis the data relating to the patient to whom said result relates.

10. A data processing system for data management in an analytical laboratory, comprising, in combination,

- a central electronic computer, for acquiring the data on patients on whose biological specimens the analyses are to be carried out, and for generating
30 a patient code for each patient acquired;
- means for acquiring an identification code associated with each container of a plurality of containers for laboratory analysis of biological specimens;

- means for combining each of said acquired identification codes with a corresponding patient code;
- at least one analyzer with means for reading identification codes associated with the containers which are placed in it, said analyzer carrying out at least one analysis on a biological specimen contained in the containers placed in it and supplying to said electronic computer the result of the analyses carried out, combined with data capable of associating said result with the patient to whom the biological specimen belongs.

11. The system according to Claim 10, comprising means for receiving from said at least one analyzer the result of said at least one analysis combined with the identification code of the container in which the analyzed biological specimen is placed, said means being programmed to associate said result with the patient code relating to the identification code combined with the result of the analysis, to send the result of the analysis combined with the patient code to said central electronic computer.

12. The system according to Claim 10, in which the result of the analysis, combined with the identification code of the corresponding container, is sent to said central computer, the central computer being programmed to associate, by means of the combination of the patient code with the identification code, each identification code - and consequently the result of the analysis - with the patient code of the patient whose biological specimen is contained in the container identified by said identification code.

13. A container for laboratory analysis of biological specimens, characterized in that it is provided with a unique machine-readable identification code.

14. The container according to Claim 13, characterized in that said identification code is applied to said container during the production of the container.

15. The container according to Claim 13 or 14, characterized in that said identification code is a bar code.

16. The container according to Claim 13, 14 or 15, characterized in that it includes means for determining an expiry date.



17. A set of containers for laboratory analysis of biological specimens, characterized in that each of said containers has a unique identification code which is different from the identification codes of the other containers of said set and is machine-readable.

5 18. The set of containers according to Claim 17, characterized in that said identification code is applied to said containers during the production of the containers.

19. The set of containers according to Claim 17 or 18, characterized in that said identification code is a bar code.

10 20. The set of containers according to Claim 17, 18 or 19, characterized in that each container is provided with means for determining an expiry date.

Fig.1

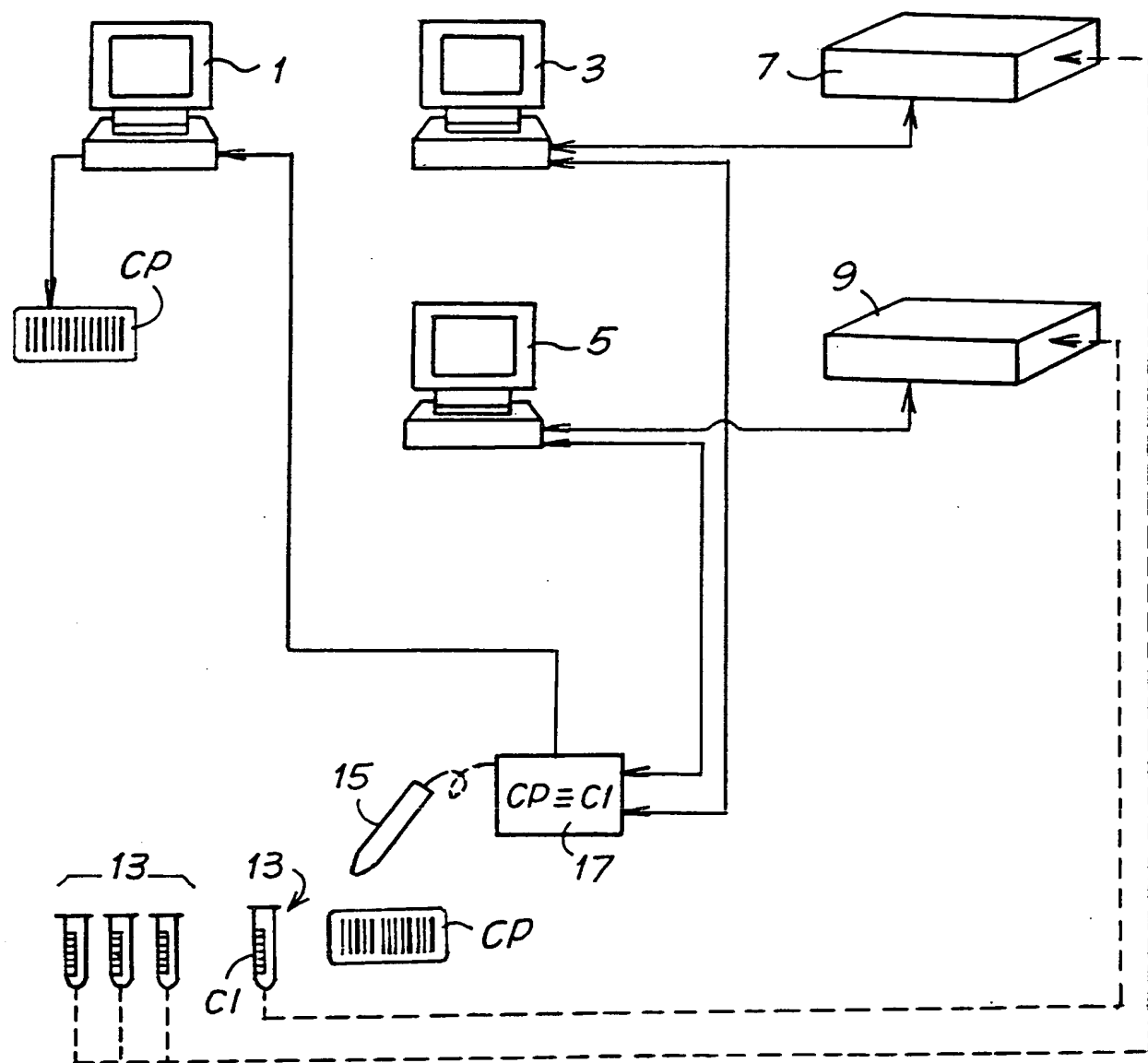


Fig. 2

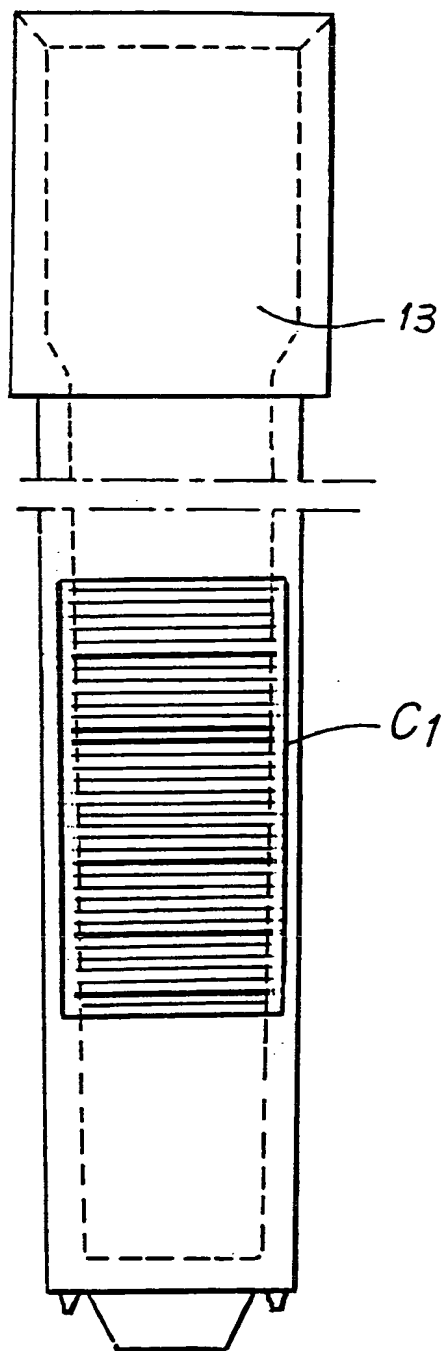




Fig. 3

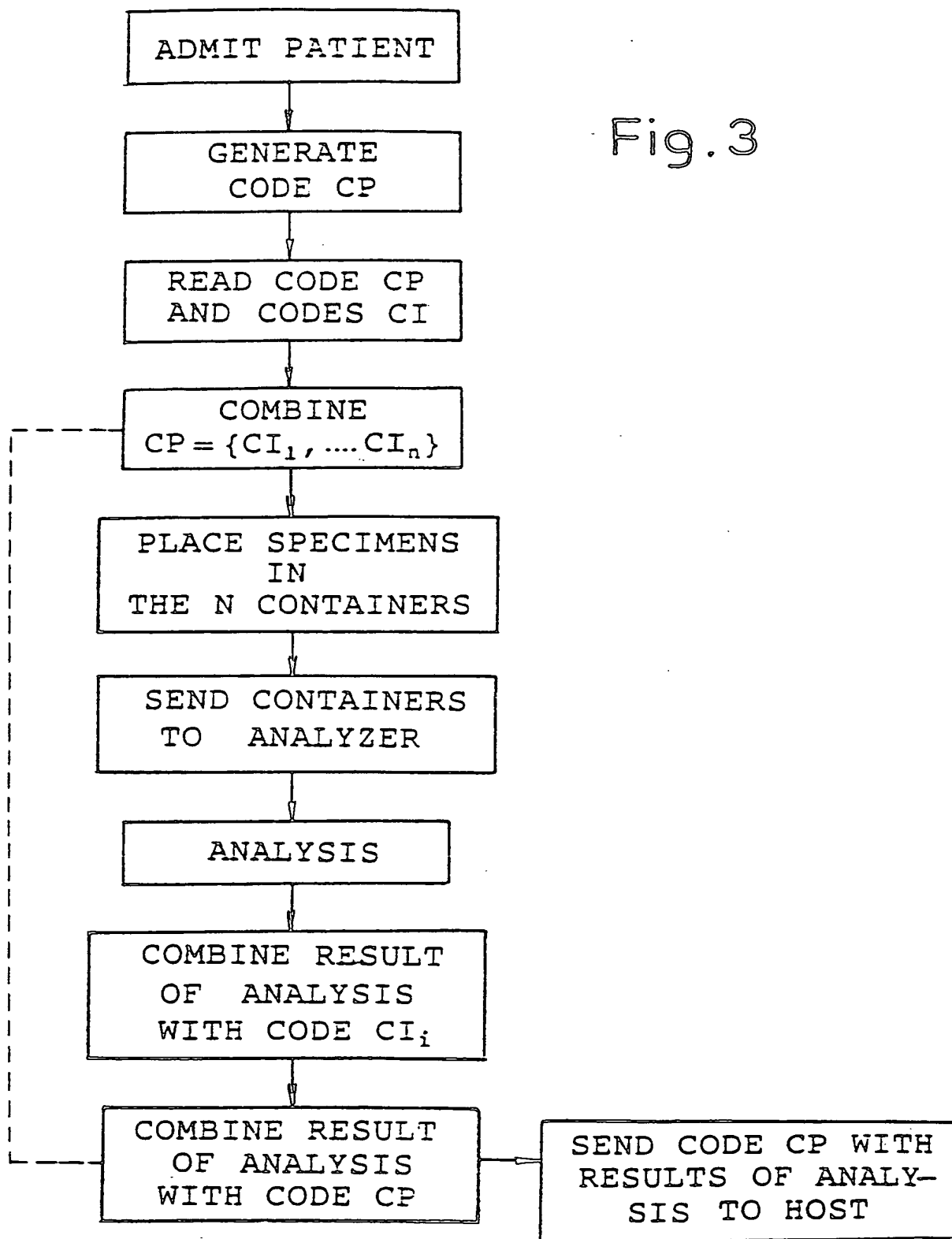
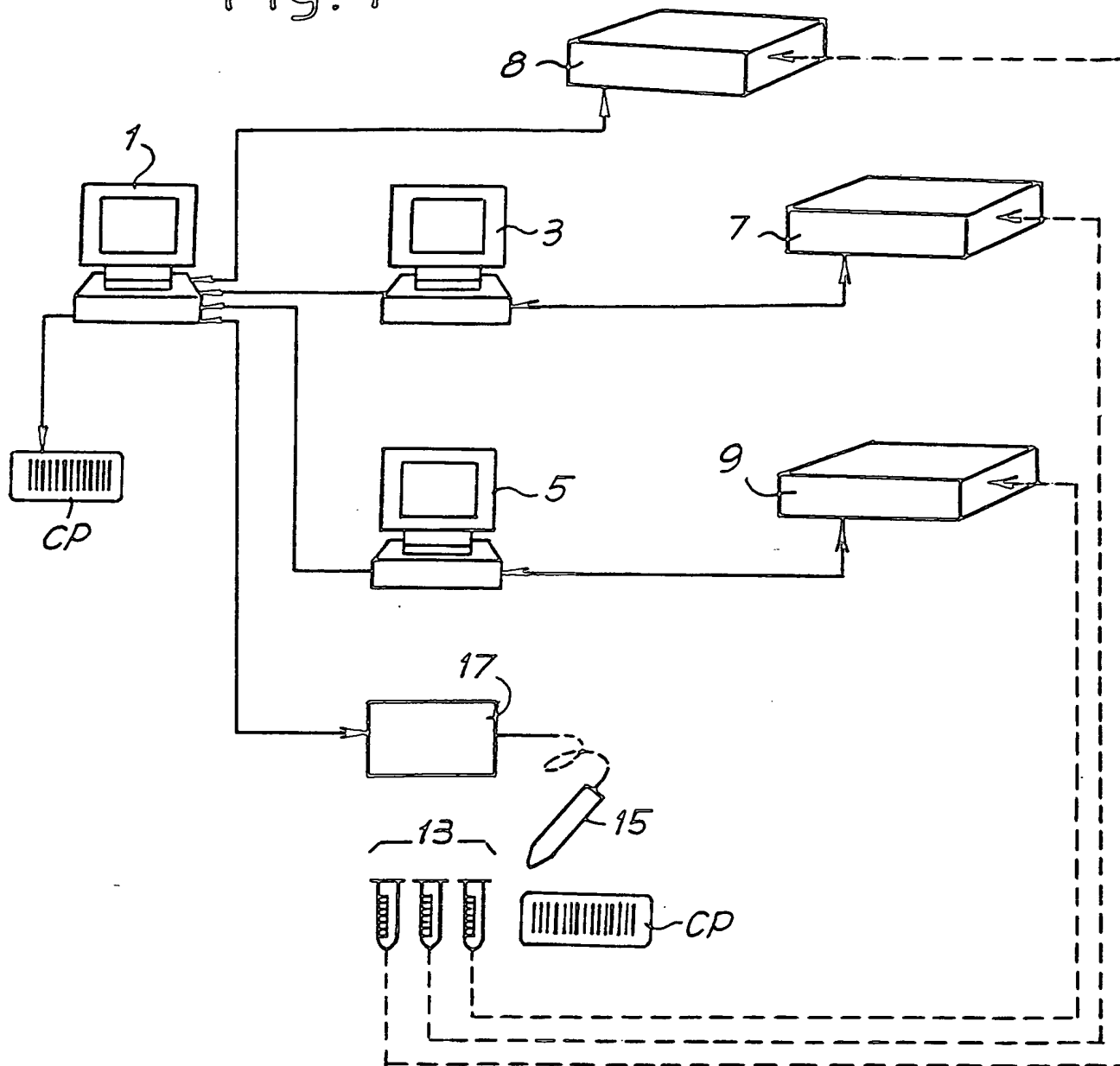
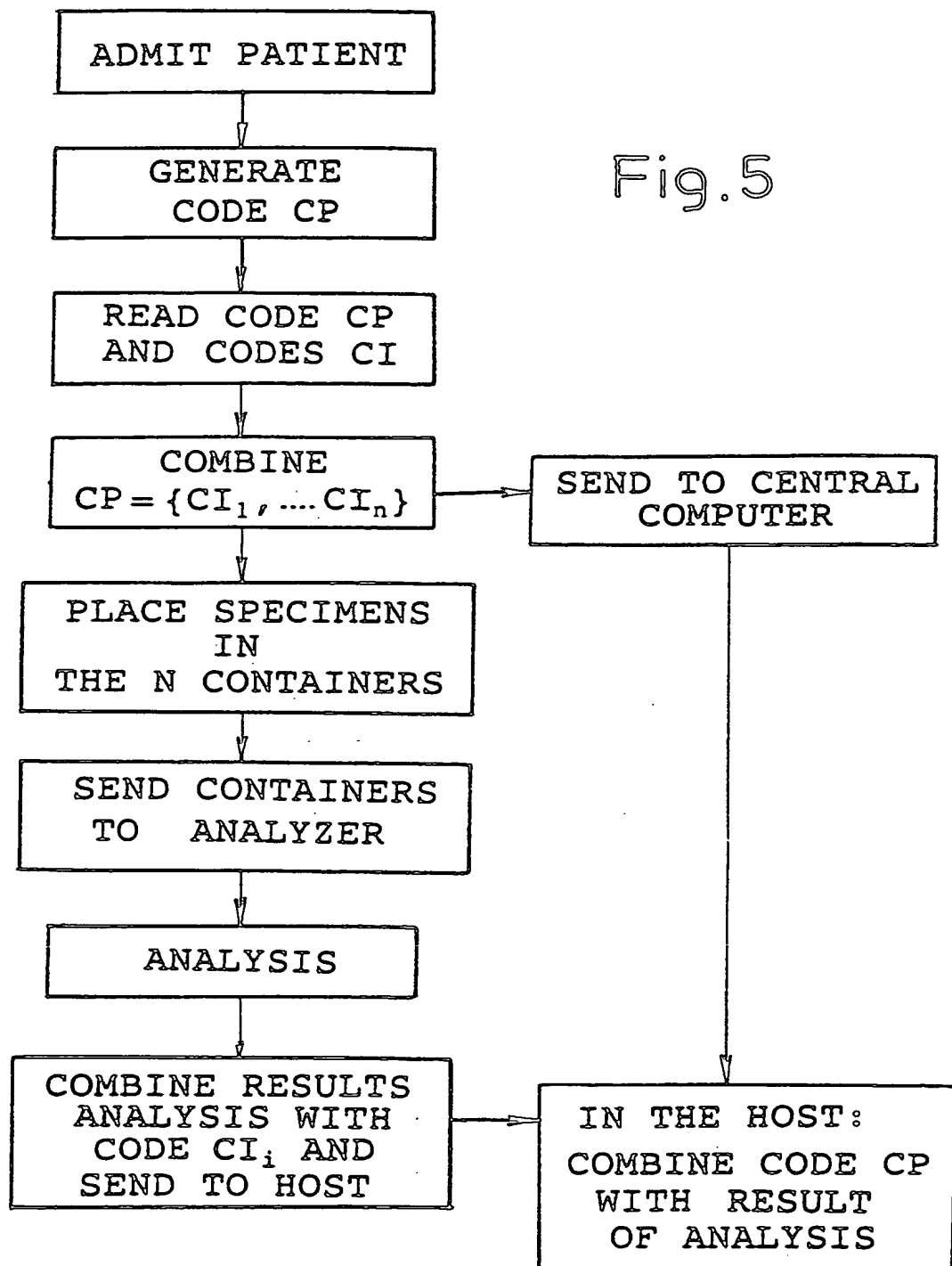




Fig. 4





(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
22 March 2001 (22.03.2001)

(10) International Publication Number
WO 01/20532 A3

PCT

- (51) **International Patent Classification⁷:** G06F 19/00.
B01L 3/14

(21) **International Application Number:** PCT/IT00/00359

(22) **International Filing Date:**
12 September 2000 (12.09.2000)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
FI99A000191 15 September 1999 (15.09.1999) IT

(71) **Applicant (for all designated States except US):** DIESSE
DIAGNOSTICA SENESE S.P.A. [IT/IT]; Via San Vit-
tore, 36/1, I-20123 Milano (IT).

(72) **Inventors; and**

(75) **Inventors/Applicants (for US only):** COCOLA, Adriano
[IT/IT]; Via San Marco, 110, I-53100 Siena (IT). MEL-
ONI, Michele [IT/IT]; Piazza F.B. Petrucci, 18, I-53100
Siena (IT).

(74) **Agents:** MANNUCCI, Michele et al.; Via della Scala, 4,
I-50123 Firenze (IT).

(81) **Designated States (national):** AE, AL, AM, AT, AU, AZ,
BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK,
DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL,
IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU,
LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT,
RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA,
UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States (regional):** ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW). Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM). European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE). OAPI patent (BF, BJ, CF, CG,
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

(88) **Date of publication of the international search report:**
11 April 2000

Published:

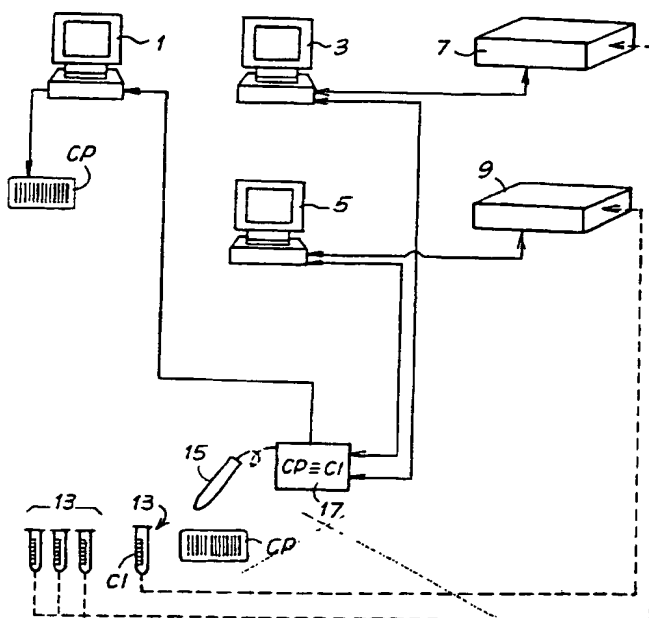
— *with international search report*

(88) Date of publication of the international search report:

11 April 2002

[Continued on next page]

(54) Title: METHOD AND MEANS FOR DATA MANAGEMENT IN A LABORATORY



(S7) Abstract: A data processing system for data management in an analytical laboratory is described, and comprises, in combination, a central electronic computer (1) for acquiring the patient data, and for generating a patient code (CP) for each patient acquired; means (15) for acquiring an identification code (CI) associated with each container (13) for laboratory analysis; means (17) for combining each of said acquired identification codes with a corresponding patient code; at least one analyzer (7; 9) which carries out at least one analysis on a biological specimen contained in the containers placed in it.

WO 01/20532 A3



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No

PCT 00/00359

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G06F19/00 B01L3/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B01L G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX, IBM-TDB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 831 006 A (CHAFFIN J ET AL) 20 August 1974 (1974-08-20)	1-3,5,6, 8-13,17
Y	abstract	4,7, 14-16, 18-20
	column 1, line 55 -column 14, line 33; figures 1-17	
Y	WO 99 41014 A (KNEPPLE RONNY ;RIEGGER HUBERT (DE); BODENSEEWERK PERKIN ELMER CO () 19 August 1999 (1999-08-19) page 1, line 1 -page 7, line 25; figures 1,2	4,7, 14-16, 18-20
A	US 4 857 713 A (BROWN JACK D) 15 August 1989 (1989-08-15) the whole document	1,10,13, 17
	--- -/-	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

26 November 2001

Date of mailing of the international search report

04/12/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Schenkels, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT 00/00359

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 510 615 A (NEELEY WILLIAM E ; JONES WILLIAM W (US)) 28 October 1992 (1992-10-28) abstract ---	1,10,13, 17
A	EP 0 819 470 A (TECHNO MEDICA CO LTD) 21 January 1998 (1998-01-21) column 2, line 45 -column 7, line 54; figures 1-9 -----	1,10,13, 17

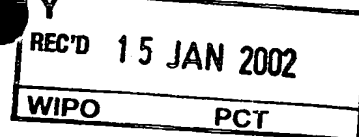
INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT 00/00359

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3831006	A	20-08-1974	AU 6383973 A CA 1002205 A1 DE 2402492 A1 FR 2214926 A1 GB 1414765 A IT 1026015 B JP 49106395 A	26-06-1975 21-12-1976 25-07-1974 19-08-1974 19-11-1975 20-09-1978 08-10-1974
WO 9941014	A	19-08-1999	DE 19806049 A1 AU 2833699 A WO 9941014 A1 EP 0975428 A1	19-08-1999 30-08-1999 19-08-1999 02-02-2000
US 4857713	A	15-08-1989	NONE	
EP 0510615	A	28-10-1992	US 5164575 A EP 0510615 A1	17-11-1992 28-10-1992
EP 0819470	A	21-01-1998	EP 0819470 A1	21-01-1998



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 46664+A	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IT00/00359	International filing date (day/month/year) 12/09/2000	Priority date (day/month/year) 15/09/1999
International Patent Classification (IPC) or national classification and IPC G06F19/00		
Applicant DIESSE DIAGNOSTICA SENESE S.P.A et al.		



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 14 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 05/04/2001	Date of completion of this report 11.01.2002
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Barba, M Telephone No. +49 89 2399 2732 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT00/00359

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-16 as originally filed

Claims, No.:

1-20 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT00/00359

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-3, 5, 6, 8-13, 17
Inventive step (IS)	Yes:	Claims
	No:	Claims 4, 7, 14-16, 18-20

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IT00/00359

Industrial applicability (IA) Yes: Claims 1-20
 No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet



Reference is made to the following documents:

D1: US-A-3 831 006 (CHAFFIN J ET AL) 20 August 1974 (1974-08-20)

D2: WO 99 41014 A (KNEPPLE RONNY ;RIEGGER HUBERT (DE);
BODENSEEWERK PERKIN ELMER CO () 19 August 1999 (1999-08-19)

Re Item IV

Lack of unity of invention

- 1 In the opinion of this International Preliminary Examining Authority the present application lacks unity within the meaning of Rule 13.1 PCT, the reasons therefor being the following.
 - 1.1 Rule 13.1 states that an international application should relate to only one invention or, if there is more than one inventions that the inclusions of those inventions in one international application is only permitted if all the inventions are so linked as to form a single general inventive concept.
In case of second it may give rise to a plurality of independent claims in the same category.
 - 1.2 Rule 13.2 specifies the circumstances according to which the requirements of unity of inventions have to be considered as fulfilled. It states that unity of inventions exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features, wherein special technical features are defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.
Therefore, it is essential that a single general inventive concept link the various independent claims both in the same category and in different categories.
 - 1.3 Lack of unity of inventions may also become apparent "a posteriori", that is after taking into consideration the prior art, when a document cited shows that the common matter of the independent claims is well known and the remaining

subject matter of each independent claims differs from that one of the others without there being any unifying novel or inventive concept common to all and therefore there is no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving the independent claims without a single general inventive concept.

- 2 For the present application as originally filed, it appears that two inventions can be identified: a first invention related to the subject matter of present independent claim 1 and dependent claims 2 to 12 and a second invention related to present independent claims 13 and 17 and dependent claims 14 to 16 and 18 to 20 respectively.
 - 2.1 The subject matter of present independent claims 1 and 10 is directed to a method and a system for managing data of an analytical laboratory.
The method of claim 1 comprises a step of associating to each container of a plurality of containers an identification code, a step of associating to each patient an identification code, a step of generating for each used container a code as a combination of said patient code and said container code, a step of associating for each used container the results of the test carried out on the sample contained in said container together with said combination code and enter said data into a data processing system.
Independent claim 10 is an apparatus claim corresponding to method claim 1.
 - 2.2 The subject matter of present independent claim 13 is directed to a container for biological specimens provided with an identification code machine readable.
The subject matter of present independent claim 17 is directed to a plurality of containers for biological specimens wherein each container of said plurality of containers is provided with an unique identification code machine readable.
- 3 The common concept and technical relationship linking together said two inventions of the present application as specified by the subject matter of independent claims 1, 10, 13 and 17 can be identified as represented by the

following technical features:

- i) a container for biological specimens provided with an unique identification code machine readable.
- 3.1 Document D1 discloses (see abstract, from column 1 line 55 to column 2 line 15; column 3 lines 17 to 30; column 3 lines 31 to 37; from column 4 line 55 to column 5 line 57) a specimen identification system wherein machine readable labels permanently containing encoded unique number are attached to each container for biological specimen for a laboratory analyser.
- 3.2 Therefore the above mentioned common concept linking together the subject matter of independent claims 1, 10, 13 and 17 is not novel because already disclosed by document D1.
- 3.3 The requisite unity of invention (Rule 13.1 PCT) therefore no longer exists inasmuch as a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 13.2 PCT does not exist between the subject-matter of independent claims 1, 10, 13 and 17. Therefore, this International Preliminary Examining Authority considers that the following separate inventions are not so linked as to form a single general inventive concept:
- i) method and a system for managing data of an analytical laboratory wherein for each used container the results of the test carried out on the sample contained in said container is associated together with a combination code comprising a patient identification code and a container identification code (present independent claim 1 and independent claim 10 together with dependent claims 2 to 9 and 11 to 12);
 - ii) a container for biological specimens provided with an unique identification code machine readable (present independent claim 13 and independent claim 17 together with dependent claims 14 to 16 and 18 to 20).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 4 The present application does not meet the requirements of Article 33 (2) PCT, because the subject matter of present independent claim 1 is not new, the reasons therefor being the following.
- 4.1 Document D1, which is provisionally considered as the closest prior art, discloses (see from column 1 line 55 to column 2 line 15; from column 3 line 1 to column 5 line 57; from column 8 line 15 to column 10 line 56; from column 11 line 60 to column 14 line 5) a method for managing data of an analytical laboratory comprising the following steps:
- i) associating to each container of a plurality of containers an identification code (see abstract, from column 1 line 55 to column 2 line 15; column 3 lines 17 to 30; column 3 lines 31 to 37; from column 4 line 55 to column 5 line 57);
 - ii) associating to each patient an identification code (see abstract; column 1 lines 65 to 67; column 3 lines 1 to 16; column 4 lines 15 to 19; column 12 lines 7 to 15);
 - iii) generating for each used container a code as a combination of said patient code and said container code (see abstract; column 3 lines 38 to 50; column 4 lines 16 to 34; from column 11 line 60 to column 14 line 5);
 - iv) associating for each used container the results of the test carried out on the sample contained in said container together with said combination code and enter said data into a data processing system (see abstract; from column 11 line 60 to column 14 line 5).

Thus, the subject matter of present independent claim 1 lacks novelty against the method known from document D1 (Article 33 (2) PCT).

- 5 Dependent claims 2 and 3 do not contain any features which, in combination with

the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, because their features are also disclosed in document D1 (see from column 1 line 55 to column 2 line 15; from column 3 line 1 to column 5 line 57; from column 8 line 15 to column 10 line 56; from column 11 line 60 to column 14 line 5).

- 5.1 Thus, the subject matter of present dependent claims 2 and 3 lacks novelty against the method known from document D1 (Article 33 (2) PCT).

- 6 Dependent claims 4 and 7 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows.

- 6.1 Document D1 discloses a method from which the subject matter of claims 4 and 7 differs only in that the features concerning an identification code placed on said container at the time of the production of said container and the use of bar codes to reproduce the patient code and the container code in order to be optically read, are omitted.

However, these features have already been employed for the same purpose in a similar method, see document D2 (from page 1 line 1 to page 7 line 25; figure 1 and 2).

It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a method according to document D1, thereby arriving at a method according to claims 4 and 7.

The subject matter of dependent claims 4 and 7 does therefore not involve an inventive step (Article 33(3) PCT).

- 7 Dependent claims 5 and 6 and dependent claims 8 to 9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, because their features are also disclosed in document D1 (see inter alia from column 4 line 55 to column 6 line 12; column 3 lines 38 to 50; column 4 lines 16 to 34; from column 11 line 60

to column 14 line 5).

7.1 Thus, the subject matter of present dependent claims 5 and 6 and claims 8 to 9 lacks novelty against the method known from document D1 (Article 33 (2) PCT).

8 Insofar as the present text of claims 10 to 12 can be understood (see Item VIII below) it appears that these claims are the apparatus claim corresponding to method claims 1 to 3, 5 to 6 and 8 to 9.
Therefore, all the objections above raised in paragraph 4 to 5.1 and 7 to 7.1 of this International Preliminary Examination Report apply in their entirety also to the subject matter of claims 10 to 12.

8.1 The subject matter of claims 10 to 12 does not meet the requirements of novelty as set out in Article 33 (2) PCT against the system known from D1.

9 Insofar as the present text can be understood (see Item VIII below) , it appears that the present application does not meet the requirements of Article 33 (2) PCT, because the subject matter of present independent claim 13 is not new, the reasons therefor being the following.

9.1 Document D1 discloses (see abstract, from column 1 line 55 to column 2 line 15; column 3 lines 17 to 30; column 3 lines 31 to 37; from column 4 line 55 to column 5 line 57) a specimen identification system wherein machine readable labels permanently containing encoded unique number are attached to each container for biological specimen for a laboratory analyser.

9.2 The subject matter of independent claim 13 does not meet the requirements of novelty as set out in Article 33 (2) PCT against the container for laboratory analysis known from D1.

10 Insofar as the present text can be understood (see Item VIII below) it appears that dependent claims 14 to 16 do not contain any features which, in combination with



the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows.

10.1 Document D1 discloses a system from which the subject matter of claims 14 to 16 differs only in that the features concerning an identification code placed on said container at the time of the production of said container, and the use of bar codes to reproduce the patient code, the container code and a container expiration date in order to be optically read are omitted.

However, these features have already been employed for the same purpose in a similar system, see document D2 (from page 1 line 1 to page 7 line 25; figure 1 and 2).

It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a system according to document D1, thereby arriving at a system according to claims 14 to 16.

The subject matter of dependent claims 14 to 16 does therefore not involve an inventive step (Article 33(3) PCT).

11 When considering the similarities in structures (see Item VIII below) the same type of objections above raised in paragraphs 9 to 10.1, are also considered valid for the subject matter of claims 17 to 20.

11.1 Thus, claims 17 to 20 do not meet the requirements of novelty and inventive step as set out in Article 33 (2) and (3) PCT against the system known from document D1 and document D2.

11.2 With regard to the assessment of the present claims 1 to 20 on the question whether they are industrially applicable, the following is stated.

With regard to the subject matter of present claims 1 to 12, it relates to method and a system for managing data of an analytical laboratory wherein for each used container the results of the test carried out on the sample contained in said container is associated together with a combination code comprising a patient identification code and a container identification code, therefore it fulfills the



requirements of industrial applicability as set out in Article 33 (4) PCT.
With regard to the subject matter of present claims 13 to 20, it relates to a container for biological specimens provided with a unique identification code machine readable, therefore it also fulfills the requirements of industrial applicability as set out in Article 33 (4) PCT.

Re Item VII

Certain defects in the international application

- 12 Present independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
- 12.1 Furthermore, the features of present claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 12.2 It is not clear from the description which features of the claimed subject matter are known from documents D1 and D2 (see the PCT Guidelines PCT/GL/3 III, 2.3a).
- 12.3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

- 13 Dependent claim 6 is not clear and as such it does not fulfill the requirements of clarity as set out in Article 6 PCT, the reasons therefor being the following.

- 13.1 The term "at least" used in claim 6 is vague and unclear and leaves the reader in doubt as to the extent of the subject matter claimed, which is against the provisions of Article 6 PCT.
- 14 Independent claim 10 is also unclear and therefore, it does not meet the requirements of Article 6 PCT for the following reasons.
- 14.1 Some of the features in the apparatus claim 10 ("said analyser carrying out ... specimen belongs") relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.
- 15 Dependent claim 11 is also unclear because the wording "being programmed" used in claim 11 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject matter of said claim unclear (Article 6 PCT).
- 15.1 Moreover, some of the features in the apparatus claim 11 ("to associate said result ... to said central electronic computer") relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.
- 16 Dependent claim 12 is not clear and as such it does not meet the requirements of Article 6 PCT for the same reasons, mutatis mutandis, above mentioned in paragraphs 15 to 15.1.
- 17 The application does not meet the requirements of Article 6 PCT, because claims 13 and 17 are not clear.

17.1 Although claims 13 and 17 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject matter claimed and in respect of the terminology used for the features of that subject matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 13 and 17 do not meet the requirements of Article 6 PCT.

17.2 In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

18 Dependent claim 16 is not clear and therefore does not fulfill the requirements of Article 6 PCT for the following reasons.

18.1 Claim 16 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The functional statement "means for determining an expiry date" does not enable the skilled person to determine which technical features are necessary to perform the stated function.

19 When considering the similarities in structure, the same reasoning as in paragraph 18.1 above, also applies to the subject matter of dependent claim 20 (Article 6 PCT).

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 46664+A		FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IT 00/ 00359	International filing date (day/month/year) 12/09/2000	(Earliest) Priority Date (day/month/year) 15/09/1999	
Applicant DIESSE DIAGNOSTICA SENESE S.P.A.			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

- ☒ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IT 00/00359

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06F19/00 B01L3/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B01L G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX, IBM-TDB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 3 831 006 A (CHAFFIN J ET AL) 20 August 1974 (1974-08-20) abstract column 1, line 55 -column 14, line 33; figures 1-17	1-3,5,6, 8-13,17 4,7, 14-16, 18-20
Y	WO 99 41014 A (KNEPPLE RONNY ;RIEGGER HUBERT (DE); BODENSEEWERK PERKIN ELMER CO () 19 August 1999 (1999-08-19) page 1, line 1 -page 7, line 25; figures 1,2	4,7, 14-16, 18-20
A	US 4 857 713 A (BROWN JACK D) 15 August 1989 (1989-08-15) the whole document --- -/--	1,10,13, 17

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

26 November 2001

Date of mailing of the international search report

04/12/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Schenkels, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT 00/00359

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 510 615 A (NEELEY WILLIAM E ; JONES WILLIAM W (US)) 28 October 1992 (1992-10-28) abstract ---	1, 10, 13, 17
A	EP 0 819 470 A (TECHNO MEDICA CO LTD) 21 January 1998 (1998-01-21) column 2, line 45 -column 7, line 54; figures 1-9 -----	1, 10, 13, 17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

EP/IT 00/00359

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3831006	A	20-08-1974	AU 6383973 A CA 1002205 A1 DE 2402492 A1 FR 2214926 A1 GB 1414765 A IT 1026015 B JP 49106395 A	26-06-1975 21-12-1976 25-07-1974 19-08-1974 19-11-1975 20-09-1978 08-10-1974
WO 9941014	A	19-08-1999	DE 19806049 A1 AU 2833699 A WO 9941014 A1 EP 0975428 A1	19-08-1999 30-08-1999 19-08-1999 02-02-2000
US 4857713	A	15-08-1989	NONE	
EP 0510615	A	28-10-1992	US 5164575 A EP 0510615 A1	17-11-1992 28-10-1992
EP 0819470	A	21-01-1998	EP 0819470 A1	21-01-1998